JUN 2 6 2003

Portex Ltd. Wallace Dual Lumen Oocyte Retrieval Set. K 031622
510(K) Notification

SECTION 5.0 : 510K SUMMARY

DATE SUBMITTED: **10th April 2003**

SUBMITTER:
Portex Ltd
Hythe
Kent
England, CT21 6JL

CONTACT PERSON:
Mr Steve Ogilvie,
Regulatory and Scientific Affairs Director,
Portex Ltd,
Military Road,
Hythe, Kent, England. CT21 6DB
Phone 00 44 (0)1303 260551
Fax 00 44 (0)1303 262798

DEVICE NAME: Wallace Dual Lumen Oocyte Retrieval Set

COMMON NAME AND CLASSIFICATION: **Oocyte retrieval Sets.** Class II MQE CFR 884.6100

PREDICATE DEVICES:

- Wallace single lumen Oocyte Retrieval sets already marketed in the USA under K00628
- Cook Double Lumen Ovum Aspiration Needle, already marketed in the USA under K983593.

DEVICE DESCRIPTION:

The Wallace Dual Lumen Oocyte Retrieval Sets are sterile, single-use devices for ultrasound – guided transvaginal collection of Oocytes from ovarian follicles. The set consists of a dual-lumen stainless needle attached to polyurethane tubing. The needle is 33cm in length and available in 16 gauge or 17 gauge sizes, each having 1cm of echomarking at the distal tip for ultrasound reflection and a plastic hub at the proximal end for ease of guidance by hand. Retrieval tubing is attached to the proximal end of the hub and is available in two lengths, protruding a total distance of either 60cm, 75cm or 95cm until it passes through a silicone bung. The Retrieval tubing is sleeved at the needle connection with a silicone sleeve (Blue 16g, Red 17g). Flushing tubing is attached to the top of the hub and extends to either 60cm, 75cm or 95cm before it terminates in a clear female luer connector.

A pump adapter component is included in each pouch pack to allow connection of the pink female Luer connector to vacuum tubing with an internal diameter of between 4 and 10.5mm.

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INTENDED USE:

The Wallace Dual Lumen Oocyte Retrieval Sets are sterile, single-use devices for ultrasound – guided transvaginal collection of Oocytes from ovarian follicles.

TECHNOLOGICAL CHARACTERISTICS OF PROPOSED VERSUS PREDICATE DEVICES:

- The proposed device is substantially equivalent to Predicate device 1 - The Wallace single Lumen Oocyte Retrieval Sets (K00628), in all aspects except the following:
    - **Dual Lumen Needle.** The proposed device has a dual lumen needle to facilitate the flushing and retrieval of the Oocytes.
    - **Dual Lumen Needle.** Echo marking on the proposed device does not extend to the needle tip
    - **Needle hub.** The proposed device incorporates the flushing line
    - **Flushing line.** The proposed device has a separate flushing line

The following aspects are substantially equivalent to predicate device 2: The COOK Double Lumen Ovum Aspiration Needle

- The dual lumen
- The position of the Echo marking
- The Needle hub
- The flushing line

PERFORMANCE / CLINICAL DATA:

Performance data for the proposed device is shown in section 8.0 Performance.

CONCLUSION:

Comparison of the proposed device to the predicate devices supports the conclusion that the proposed device is substantially equivalent in safety and effectiveness in its intended use to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2003

Mr. Steve Ogilvie
Regulatory and Scientific
Affairs Director
Portex, Ltd,
Military Road, Hythe, Kent
CT21 6DB, England
UNITED KINGDOM

Re: K031622
Trade/Device Name: Wallace Dual Lumen
Oocyte Retrieval Sets
Regulation Number: 21 CFR 884.6100
Regulation Name: Assisted reproduction
needles
Regulatory Class: II
Product Code: 85 MQE
Dated: May 16, 2003
Received: May 23, 2003

Dear Mr. Ogilvie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K031622

Portex Ltd . Wallace Dual Lumen Oocyte Retrieval Sets, 510(K) Notification

Section 4.0: STATEMENT OF INDICATION FOR USE

510(K) Number (if known): K031622 **Page 1 of 1**

Device Name: Wallace Dual Lumen Oocyte Retrieval Sets

Indications for use:

'The Wallace Dual Lumen Oocyte Retrieval Sets are sterile single-use devices for ultrasonic-guided transvaginal collection of oocytes from the ovarian follicles.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031622